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10/584,207	11/28/2007	Terence J. Colgan	MCY5USA	3654

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HOWSON & HOWSON LLP
501 OFFICE CENTER DRIVE
SUITE 210
FORT WASHINGTON, PA 19034

EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,207	COLGAN ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,6,8,9 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,6,8,9 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

Applicant's amendment filed 18 June 2010 in response to the Office action mailed 19 March 2010 is acknowledged. Claims 10-17, 23-27, 30-39, 43-46, 48 and 49 are newly cancelled. Claims 2, 3, 4, 6, 8, 9 and 19-21 are under examination.

Rejections withdrawn

Any rejections over claim 10 are hereby withdrawn in response to Applicants' cancellation of that claim.

The text of those sections of 35 U.S.C. not included in this action can be found in a prior office action mailed 19 March 2010.

Claim Rejections - 35 USC § 102

The rejection of claims 2-4 and 8 under 35 U.S.C. 102(b) as being anticipated by Xiaoguang et al. (AJRI, 1999; 41: 204-208—on Applicants' 1449 form) as set forth in the Office action mailed 19 March 2010 is withdrawn in response to Applicants' amendment of the claims to recite endometrial cancer. Although malignant trophoblastic tumor usually occurs in the uterus, it is a malignancy of the syncytiotrophoblasts and cytotrophoblasts without formation of definite placental type villi, and thus cannot reasonably be interpreted as "endometrial cancer."

Rejections Maintained

Claim Rejections - 35 USC § 112, first paragraph – Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 2-4, 6, 8 and 9 under 35 U.S.C. 112, first paragraph, because the specification for scope of enablement is maintained in part. The specification, while being enabling for a method of screening for endometrial cancer in a subject, the method comprising, (a) detecting the levels or amount of chaperonin 10 (CPN 10) as set forth in SEQ ID NO: 1 in an endometrial tissue sample obtained from the subject and (b) comparing the levels or amount of CPN 10 in step (a) with the levels or amount of chaperonin 10 in a control endometrial tissue sample, wherein increased levels of CPN 10 protein expression in the sample obtained from the subject is indicative of endometrial cancer, does not reasonably provide enablement for the claims as broadly recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Some of the issues raised in the previous Office action have been resolved. The issue raised in point (i) regarding the breadth of the phrase, “endometrial disease” has been resolved by Applicants amendment of the claims to recite ”endometrial cancer.” Similarly, the issue raise in point (iii) regarding the recitation of "pre-determined" standards or "cut off values", has been resolved by Applicants' amendment of claim 3 deleting these terms and reciting measurement of relative protein levels of CPN 10. The concerns raised in point (ii), regarding the phrase “biological sample”; point (iv),

regarding the breadth of CPN 10 and point (v) regarding the complexity and unpredictability of proteomics technology remain and the Examiner's comments at pages 5-8 concerning these points are hereby incorporated. Finally, the Examiner noted at pages 3 and 4 of the Office action mailed 19 March 2010 in the statement of rejection that ***elevated or increased*** levels of CPN 10 are indicative of endometrial cancer.

Due to the large quantity of experimentation necessary to determine which chaperonin 10 muteins can be detected in which biological samples and shown to be differentially expressed between those patients with and without endometrial cancer and to therefore accurately predict said endometrial cancer, the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to the same; the complex nature of the invention; the unpredictable state of proteomics technology and its ability to accurately predict cancer; (the level of skill of those in the art); and the breadth of the claims which fail to recite limitations on the biological sample and the chaperonin 10 mutein, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Response to Arguments Regarding Rejection under 35 U.S.C. 112, first paragraph

Scope of Enablement Rejection

Applicants argue at top of p. 6 that the link between protein in blood and disease is tenuous until it can be established that the protein is expressed in the diseased tissue, and that the specification does teach that CPN is elevated in malignant tissue.

Applicants argue at p. 6, 1st paragraph that the teachings of Applicants' specification, taken together with public knowledge at the time the invention of the

claims was made, provide the evidence to one of skill in the art that the high levels of CPN10 from malignant endometrial tissue are found in blood (including serum) and that CPN10 would not be a non-specific biomarker if measured in blood because elevated levels of CPN 10 in blood due to endometrial cancer would be distinguishable from early pregnancy or trophoblastic tumor based on accompanying clinical indications.

These arguments have been fully considered but are not found persuasive. First, the arguments state that CPN can be measured in blood or serum, but with the exception of claim 8 and 9, the claims actually recite "biological sample", which is broader than serum or blood. As noted in the previous Office action, Yang et al. (of record—p. 637, left column) teach that "***in the future*** it may be possible to sample…endometrial cells, debris and secretions by means of a uterine lavage for proteomic analysis." Thus Applicants are arguing limitations not present in the claims. Further, with the regard to the recitation of serum in claim 8, Applicants' remarks do not address the concerns raised in Yang et al. (2004; of record), which teaches that there are "a large number of variables that determine whether discriminating features can be reproducibly obtained or not" regarding the measurement of proteins in serum to diagnose disease (p. 637, left column). This is further exacerbated by the fact that proteomics technology is complex and unpredictable (see Erika Check article in Nature—of record), which explains that the field has not yet had the opportunity to develop standards for interpreting test results. An illustrative example is given regarding internal inconsistencies in the data of an early detection test for ovarian cancer. Given the level of unpredictability of proteomics technology in diagnosis, the breadth of appropriate fragments, precursors, modified forms, chimeric forms or derivatives is exacerbated.

Applicants argue at p. 6, 2nd paragraph through p. 7, 1st paragraph that the sequences taught in the specification and the muteins associated therewith represent human CPN10 detectable by conventional assays and that the high level of skill in the art would enable one of routine skill to identify and detect a variety of suitable CPN10 sequences.

This argument has been fully considered but is not found persuasive. While the Examiner takes no issue with the assertion that the level of skill in the art is high, "the breadth of enablement is not commensurate in scope with the claims" (see MPEP 2164.06(b)). The teachings set forth in the specification provide no more than a plan or invitation for those of skill in the art to experiment using the proteomics technology to define appropriate fragments, precursors, modified forms, chimeric forms or derivatives suitable for the diagnosis of endometrial cancer. This is further exacerbated by the fact that proteomics technology is complex and unpredictable (see Erika Check article in Nature—of record), which explains that the field has not yet had the opportunity to develop standards for interpreting test results. An illustrative example is given regarding internal inconsistencies in the data of an early detection test for ovarian cancer. Given the level of unpredictability of proteomics technology in diagnosis, the breadth of appropriate fragments, precursors, modified forms, chimeric forms or derivatives is exacerbated.

Claim Rejections - 35 USC § 112, first paragraph – Total Lack of Enablement

The rejection of claims 19-21 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record and the following. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The concern raised in point (a) is resolved with the cancellation of claim 10. The point raised in (b) regarding the complexity and unpredictability of proteomics technology remains. Further, the concern raised in point (c) regarding the goals of claims 19-21 to monitor the progression of endometrial cancer (claim 19), to determine a subject in which endometrial cancer has metastasized or is likely to metastasize in the future (claim 20) and to assess the aggressiveness or indolence of endometrial cancer in a subject (claim 21) remain. Finally, the remaining issues raised in the previous scope of enablement rejection, namely, points (ii), (iv) and (v), would still be applicable even if claims 19-21 were enabled.

Due to the large quantity of experimentation necessary to determine values of chaperonin 10 that would be capable of monitoring progression of disease as recited in the claims, which cancer markers can be detected that are differentially expressed between those patients with and without endometrial disease to therefore accurately predict said endometrial disease, and which biological samples can be used to carry out the methods; the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to the same; the complex nature of the invention; the unpredictable state of proteomics technology and its ability to accurately predict cancer, (the level of skill of those in the art); and the breadth of the claims which fail to recite limitations on the biological sample, the chaperonin 10 mutein

and the cancer markers, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Response to Arguments Regarding Rejection under 35 U.S.C. 112, first paragraph

Total Lack of Enablement

Applicants argue at bottom of p. 7 and the top of p. 8 that there is no requirement in US patent law requiring that a diagnostic method for risk analysis of any cancer be 100% accurate. In clinical practice, biomarkers that are much less discriminatory, e.g., PSA or CA125, have been found to be valuable for screening subjects for diagnosis or prognosis of a cancer.

Applicants argue at p. 8 that they demonstrated that high expression of CPN 10 is a biomarker for endometrial cancer in this example and probable reasons for the less than 100% accuracy of the CPN10 biomarker in every tested instance of endometrial cancer were provided in the description. These data are sufficient to enable one of skill in the art to perform the methods claimed on suitable biological samples with a reasonable expectation of making a risk analysis or diagnosis of endometrial cancer.

These arguments have been fully considered but are not found persuasive. First, the Examiner takes no issue with Applicants' statement that there is no requirement in US patent law that a diagnostic method for risk analysis be100% accurate. However, this argument does not address the actual concern raised by the Examiner that the data presented in the specification do not demonstrate the ability of the claimed methods to differentiate between different stages of endometrial cancer or prognosticate risk. The goals of claims 19-21 are prognostic in nature and involve monitoring the progression of endometrial cancer (claim 19), determining a subject in which endometrial cancer has metastasized or is likely to metastasize in the future (claim 20) and to assessing the aggressiveness or indolence of endometrial cancer in a subject. The data presented in the specification demonstrate only a relative increase in CPN 10 protein expression in

patients with endometrial cancer vs. controls, but there are no pre-determined standards or cut off values taught that could differentiate between more and less aggressive cases of cancer. The specification does not recite cut off or predetermined values and this type of teaching would be needed in order for the skilled artisan to prognosticate risk. The methods claimed in 19-21 would require not merely screening for the possibility of endometrial cancer, but also monitoring its progression. The specification (Tables 2 and 3) only shows measurements in terms of intensity of expression and the methods are semi-quantitative. The specification does not provide a nexus between these protein measurements and the stage of endometrial cancer, cancer aggressiveness, or whether the cancer has or will metastasize. There is a need for pre-determined standards or cut-off values for the more detailed methods of monitoring progression of the disease require and one skilled in the art to undertake empirical research to establish those standards and values. The art (Yang et al. and Dube et al.—both of record) does not teach the existence of pre-determined standards or cut off values that would enable one skilled in the art to undertake the more detailed methods of monitoring progression of endometrial disease. The methods recited in claims 19-21 represent an invitation to the skilled artisan to undertake further research to discover the parameters needed to carry out the goals of the methods.

As a final point regarding Applicants' comment of the usefulness of CA125 and PSA in prognostication, it is noted that the Examiner presented an article by Erika Check that raised concerns about a proteomic assay for ovarian cancer. Further, recent recommendations by the US Preventive Services Task Force teach that PSA screening

is of uncertain value (see Lin et al., Ann Intern Med. 2008; 149: 192-199—see whole article).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 2-4, 8 and 9 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Warrington et al., 2001/0044104, published 22 November 2001 in view of zellnet.com/nss-folder/pictures/Fig1.gif, downloaded 8 March 2010 is maintained for reasons of record and the following.

Response to Arguments Regarding Rejection under 35 U.S.C. 102(b)/103(a)

Applicants argue at p. 9 as a general rule altered expression at the genetic level or level of mRNA expression, is not predictably correlated with altered expression at the protein level. In support of this submission, and cite Gry et al. 2009 "Correlations between RNA and protein expression profiles in 23 human cell lines" in BMC Genomics, 10:365 (Exhibit 1) as evidence.

This argument has been fully considered but is not found persuasive. Beer et al. (Nature Medicine, 2002; 8: 816-824) describe gene expression of genes in adenocarcinomas that is highly correlative to protein expression. Beer et al. state at p. 822, left column:

> The strong correlation of northern-blot analysis and oligonucleotide-array data for gene expression in the same samples...indicates that these studies provide robust gene-expression estimates. Immunohistochemistry using the same tumor samples in tissue arrays demonstrates protein expression within the lung tumor cells. Together, these studies indicate that many of the genes identified using gene expression profiles are likely relevant to lung adenocarcinoma, thus the authors agree that microarrays provide a reliable measure of the expression levels of the gene and can be used to identify genes whose over-expression is associated with tumors.

Further, Beer et al. discuss the high degree of accuracy with which oligonucleotide microarrays provided reliable measures of gene expression (see whole article). As early as 1999, gene expression monitoring has proven useful in the clinic. Golub et al.

(Science, 1999; 286: 531-537) report a case in which examination of the patient's gene expression profile resulted in the proper diagnosis and treatment adjustment, thereby demonstrating that "diagnosis...could benefit from a battery of expression-based predictors for various cancers." Finally, Applicants' own specification contemplates the use of microarrays in methods of diagnosis. For instance, see the specification publication beginning at paragraph [0227] wherein the use of microarrays is described.

Applicants argue at p. 9 that Warrington's Table 6 simply states that alterations in gene expression were detected generally in more than 65 different genes but that no further teaching is provided by Warrington about any of the genes in Table 6 (i.e., CPN 10), noting also Example 2; Table 3 of Warrington et al.

This argument has been fully considered but is not found persuasive. Note that it is not necessary that an anticipatory reference shall have actually been made in order to satisfy the enablement requirement. In re Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985). Further, regarding the state of the art, both Beer et al. and Golub et al. demonstrate that gene expression monitoring is highly useful in the art of cancer diagnosis.

Applicants argue at p. 9 through 10 that CPN10 is listed only once in Table 6 among 65 other genes and is nowhere mentioned again in the entire Warrington claims or disclosure and there is no indication in this simple list of which genes are obtained from the benign vs. malignant tumors. Further, there is no indication which genes of Table 6 are over-expressed or under-expressed relative to normal to permit for identification of cancer itself.

These arguments have been fully considered but are not found persuasive. Regarding the argument that CPN10 is listed only once in Table 6 among 65 other genes; Warrington performed microarray analysis, which is known to survey many genes at once. Note also MPEP 2131.02 which states that when the species is clearly

named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. Second, Warrington et al. indicate a four-fold change in expression of CPN10 in Table 6, which is not a subtle change. Third, regarding the argument that there is no indication of which genes are obtained from the benign vs. malignant tumors, as noted before, microarray analysis surveys many genes simultaneously, so it is unlikely that some genes were surveyed only in benign tissues whereas others were surveyed only in malignant as Applicants suggest. Further, according to the website downloaded 30 August 2010 at merck.com/mmpe/print/sec18/ch254/ch254d.html regarding endometrial tumors, “adenocarcinoma accounts for over 80% of all endometrial cancers” (see first page, under “Pathology"), thus it is highly likely, with greater than 80% certainty, that the tissues surveyed were adenocarcinomas. Fourth, regarding the argument that there is no indication which genes of Table 6 are over-expressed or under-expressed relative to normal to permit for identification of cancer itself, it is noted that Applicants’ own claims do not specify up- or down-regulation of CPN10, thus Applicants are arguing limitations not present in the claims.

Applicants argue at p. 10 that Warrington's additional Example 3 using matched normal and adenocarcinoma or clear cell carcinomas from more than 10 patients shows 13 different genes not listed in Table 6 and demonstrates how their expressions differ in normal vs. adenocarcinoma vs. clear cell carcinoma (Table 7). Based upon this. Applicants conclude that Warrington's resulting claims for a method for diagnosing endometrial cancer in an endometrial tissue sample teaches away from the methods of

Applicants' claims because none of the genes are listed in Table 6 (i.e., CPN 10) are tested.

This argument has been fully considered but is not found persuasive. The fact that Warrington focused on certain genes in a single example does not teach against the claimed methods. Warrington et al. named genes that were changed in endometrial tumors and performed an illustrative example. It should also be noted that Cyclin A1; HOX are among two genes that appear in both Tables 6 and 7. Note further, MPEP 2123 I and II that non-preferred embodiments constitute prior art:

> A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also >Upsher-Smith Labs. v. Pamlab, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005)(reference disclosing optional inclusion of a particular component teaches compositions that both do and do not contain that component);< Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").
>
> Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material. The applied prior art reference taught a printed circuit material similar to that of the claims but impregnated with polyester-imide resin instead of epoxy. The reference, however, disclosed that epoxy was known for this use, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," but are inferior to circuit boards impregnated with polyester-imide resins. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was

> insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Finally, the rejection over Warrington et al. was made under both 35 U.S.C. 102(b) and 103(a), thus the anticipatory part of the reference is that genes were named and analysis was performed thus arguments that Warrington et al. "teach away" are not germane to this aspect of the rejection, which was made under section 102.

In summary, the preponderance of the evidence suggests that the rejection under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) should be maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 9:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest

/Elizabeth C. Kemmerer/

Elizabeth C. Kemmerer, Ph.D.

Primary Examiner, Art Unit 1646